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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,608	08/28/2003	Jean-Pol Cassart	B45300-1	8978

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,608	CASSART ET AL	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claim 1 links the inventions of groups A-B. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

Group A. Claims 1-5, 14-16, drawn to a method of treating colorectal, breast or lung cancer, using SEQ ID NO:2, classified in class 514, subclass 2. A method treating each cancer constitutes a single, distinct invention.

Group B. Claims 1-5, 14-16, drawn to a method of preventing colorectal, breast or lung cancer, using SEQ ID NO:2, classified in class 514, subclass 2. A method preventing each cancer constitutes a single, distinct invention.

Claim 1 links the inventions of group C and group D. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the

allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

Group C. Claims 1-4, drawn to a method for treating colorectal, breast or lung cancer, using SEQ ID NO:3, 7, 10, 11, 12 or 14, classified in class 514, subclass 2. A method of treating each cancer, using each sequence constitutes a single distinct invention.

Group D. Claims 1-4, drawn to a method for preventing colorectal, breast or lung cancer, using SEQ ID NO:3, 7, 10, 11, 12 or 14, classified in class 514, subclass 2. A method of preventing each cancer, using each sequence constitutes a single distinct invention.

Claim 6 links the inventions of group E. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 6. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

Group E. Claims 6-9, drawn to a method for inducing an immune response, using a fragment of SEQ ID NO:2, which is SEQ ID NO: 16-33, classified in class 514, subclass 2. A method using each fragment constitutes a single, distinct invention.

Claim 10 links inventions of groups F-G. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

Group F. Claims 10-13, drawn to a method for treating colorectal, breast or lung cancer, using the polynucleotide SEQ ID NO:1, classified in class 514, subclass 4. A method treating each cancer constitutes a single, distinct invention.

Group G. Claims 10-13, drawn to a method for preventing colorectal, breast or lung cancer, using the polynucleotide SEQ ID NO:1, classified in class 514, subclass 4. A method for preventing each cancer constitutes a single, distinct invention.

Claim 17 links inventions of group H. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 17. Upon the allowance

of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

Group H. Claims 17-18, drawn to a fragment of SEQ ID NO:2, classified in class 530, subclass 300. Each fragment of SEQ ID NO:2, SEQ ID NOs: 16-33, constitutes a single, distinct invention.

Group I. Claim 19, drawn to the polypeptide SEQ ID NO:35, classified in class 530, subclass 350.

Group J. Claims 20-22, drawn to a polynucleotide encoding SEQ ID NO:35, a vector, a host cell, classified in class 536, subclass 23.1.

The inventions are distinct, each from each other because of the following reasons:

A. The inventions of Groups A-G are materially distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The inventions of Groups A-G are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for

success. The methods of treating and preventing cancer are distinct, because they use different populations of treated patients, i.e. those who already have cancer, versus those who are at risk of cancer. Similarly, the methods of treating or preventing different cancers are distinct, because they use different treated populations having different types of cancer, or at risk of different types of cancer. Further, the method of treating or preventing cancer are distinct from each other, because each method uses a different peptide or polypeptide, or different polynucleotide, all having different structure, and different functions, or different effects. In addition, the treating or preventing method of groups A-B, which uses the full length SEQ ID NO:2, is distinct from the method of group E, which use a fragment of SEQ ID NO:2, because a fragment of SEQ ID NO:2 has different mode of operation as compared to the full length sequence, in view that it does not have the same structure and biological activity of the full length sequence SEQ ID NO:2. Thus, each group is unrelated as they comprise distinct steps and utilize different products, which demonstrates that each method has different mode of operation. For these reasons the Inventions A-G are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The examination of all groups would require different searches in the U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. There may be journal articles devoted solely to a method of treating or preventing cancer using one polypeptide, which would not have described methods of treating or preventing cancer using a fragment of said polypeptide, or other polypeptide, or the encoding polynucleotide, or vice versa. Similarly, there may be journal articles devoted solely to a method of treating or preventing one

cancer, which would not have described methods of treating or preventing another cancer. As such, it would be burdensome to search the inventions of Groups I-IX together.

B. Inventions of Groups H-J represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. Each sequence, unless otherwise shown, is independent and distinct. That is the basis of the MPEP rule regarding sequence restriction, which notes "These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide or polypeptide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 (See MPEP 2434)." Moreover, different fragments of SEQ ID NO:2, or different polypeptides are distinct from each other, because although the different sequences could be used for eliciting T cell response, or treating cancer, however, they do not share a substantial structure feature disclosed as being essential for eliciting T cell response or treating cancer. For unity of invention, the compounds have to (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential for that utility. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984) (MPEP 803.02).

Further, the peptide or polypeptide of Groups H-I and the polynucleotide of Group J are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA. Further, the polynucleotide can be used for hybridization screening, the polypeptide can be used for methods

of treatment. Furthermore, neither of the inventions is essential for the production of the other and is not capable of use with the other and they have different modes of operation, different functions, or different effects. While a polypeptide of group I can made by methods using the corresponding polynucleotide of Group J, it can also be recovered from a natural source using biochemical means. For instant, the polypeptide can be isolated, using affinity chromatography.

Furthermore, searching the inventions of all groups together would impose a serious search burden. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. In the instant case, the search of the different peptides, polypeptides and the polynucleotides are not coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to one peptide or polypeptide, which would not have described another, different peptide or polypeptide, or the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups H-J together.

The invention of Group H and the method of Group E are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product (see MPEP 806.05(h)). In the instant case the peptides product as claimed can

be used in a materially different process such as in making an antibody, in addition to treating a disorder.

Searching the inventions of Groups E, H together would impose serious search burden. The inventions of Groups E, H have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the peptide and the method of inducing an immune response, using the peptide are not coextensive. The search for Group E would require a text search for the method of inducing an immune response, or a method for treating cancer, in addition to a search for the peptide. Moreover, even if the peptide product were known, the method of inducing an immune response or treating cancer, which uses the product may be novel and unobvious, in view of the preamble or active steps.

Inventions of Group H and Groups A-D, F-G are unrelated because the product of group H is not used or otherwise involved in the processes of groups A-D, F-G.

Inventions of Groups I-J and Groups A-G are unrelated because the product of groups I-J is not used or otherwise involved in the processes of groups A-G.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn

process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

June 21, 2006

SUSAN UNGAR, PH.D
PRIMARY EXAMINER